DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 529

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Certifier R. LEDESMA

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from DEC International, Inc., to Pharmacia & Upjohn Co.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–101), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: DEC International, Inc., 1919 South Stoughton Rd., P.O. Box 8050, Madison WI 53708–8050, has informed FDA that it has transferred ownership of, and all rights and interests in, NADA 141–200 for EAZI–BREED CIDR Progesterone Intravaginal Inserts to Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199. Accordingly, the agency is amending the regulations in 21 CFR 529.1940 to reflect the transfer of ownership.

Following this change of sponsorship, DEC International, Inc., is no longer the sponsor of any approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for DEC International, Inc.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 529

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 529 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for "DEC International, Inc." and in the table in paragraph (c)(2) by removing the entry for "067080".

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 529.1940 [Amended]

4. Section 529.1940 *Progesterone intravaginal inserts* is amended in paragraph (b) by removing "067080" and by adding in its place "000009".

Dated: July 17, 2002.

Alan Rudman,
Acting Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

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